Marked version of the amended claims, showing all changes

1. (Amended) A biocompatible tissue repair stimulating implant, comprising:

a bioabsorbable polymeric foam component having pores with an open cell pore structure;

a reinforcing component formed of a biocompatible, mesh-containing material having a mesh density in the range of about 12 to 80%,

wherein the foam component is integrated with the reinforcing component such that the pores of the foam component penetrate the mesh of the reinforcing component and interlock with the reinforcing component; and

at least one biological component in association with the implant.

18-53. Canceled.

REMARKS

The outstanding Office Action addresses and rejects claims 1-17. Applicants respectfully request reconsideration of the present application in view of the amendments set forth above and the remarks below.

Claim 1 has been amended to clarify that the mesh reinforcing material has a mesh density in the range of about 12 to 80%. Support for this amendment can be found throughout the specification, for example at page 4, lines 6-10. No new matter has been added.

Non-elected claims 18-53 have been canceled without prejudice.

35 U.S.C. §103(a) Claim Rejections

Rejection Pursuant to Bell et al.

The Examiner rejects claims 1-17 pursuant to 35 U.S.C. 103(a), alleging that the claims are obvious over U.S. Patent 6,179,872 to Bell et al. (Bell).

In particular, the Examiner argues that Bell discloses a biopolymer mat that has low density and high porosity, and that the matt can incorporate fiber structures to achieve general reinforcement, including polymer mesh. The Examiner further states that Bell includes the biological components required by the claims.

Applicants traverse this rejection and submit that the pending claims distinguish over the Bell reference.

The claimed invention is directed to a biocompatible tissue implant having a polymeric foam component and a mesh-reinforcing component. The claims require that the foam component be integrated with the mesh component such that the pores of the foam penetrate the openings in the mesh component and interlock with the mesh component. The mesh density must be in the range of about 12 to 80% to enable such penetration of the mesh by the pores of the foam component and this mesh density requirement is likewise claimed.

The pending claims also require a biological component to be present within the tissue implant.

Applicants have discovered that allowing the foam component to bond through and interlock with the mesh-reinforcing component greatly improves the strength of the implant. The interlocking nature of the pores of the foam with the mesh is an important feature of the claimed invention that contributes to enhanced properties. This interlocking of the pores with the mesh is made possible by the mesh having a mesh density, or measure of mesh open space, in the claimed range. Applicants have found that an interlocking structure is not possible without a mesh density in the claimed range.

While Bell generally teaches a biocompatible mat including a biological component, Bell fails to teach the claimed invention in which the pores of the foam component penetrate and interlock with the mesh of the reinforcing component. The fact that Bell may disclose that its matt is formed of *materials* similar to those used to form the foam layer of the claimed invention does not establish a similar *construction* of Bell's matt. Although Bell teaches the use of a biopolymer matt and a biopolymer foam, there is no disclosure or suggestion in Bell that pores of the foam layer should actually penetrate through the openings of the reinforcing layer. And, since this phenomenon is dependent on physical properties, such as mesh density, this type of penetration is not an inherent feature of Bell's matt. The layers of foam may simply be adhered to the surface of the reinforcing layer, or the reinforcement component may be enveloped within the foam layer without any interlocking. In fact, nowhere does the language in Bell disclose or suggest that the pores of a foam layer are bonded through or interlocked with a mesh layer

Bell also fails to teach or suggest a reinforcing component having a 12 to 80% mesh density. The mesh density is a measure of the amount of open surface space compared to the total amount of surface space. Even though the reinforcing layer of Bell may have some openings, without the proper mesh density the pores of the foam cannot penetrate through the reinforcing layer.

Rejection Pursuant to Arnold

Claims 1-17 are also been rejected pursuant to 35 U.S.C. 103(a) as being obvious over Arnold, U.S. Patent No. 5,766,631. The Examiner argues that Arnold discloses an implant comprising bioabsorbable microspheres of variable size and volume which can be reinforced with a mesh.

However, Arnold does not disclose or suggest a foam component interlocked with a mesh reinforcing component, where the mesh component has a mesh density of 12 to 80%. In fact, this limitation relating to the interlocking of the foam and the mesh is entirely ignored by the examiner, and no allegation is made that Arnold discloses or suggests such a feature.

The pending claims require a biocompatible tissue repair implant in which a foam component is integrated with a reinforcement component such that the pores of the foam component penetrate the mesh and interlock with the mesh. Further, the mesh density of the reinforcing component must be in the range of 12-80%. Arnold fails to disclose or suggest any construction that even remotely resembles the claimed invention. Arnold instead discloses microspheres which are essentially adhered together by a matrix to form a wound implant material. Although, the wound implant material may be reinforced with a mesh material, Arnold fails to disclose how the mesh material is connected with the microsphere/matrix material. Arnold also fails to disclose or suggest anything about the mesh density of the mesh component.

Arnold also fails to disclose or suggest any relationship between a mesh reinforcing material and a foam component in which the foam is integrated with the reinforcing component such that the pores of the foam penetrate the mesh and interlock with the mesh. The mere presence in Arnold of a mesh and a foam does not establish the interlocking integration of the mesh and the foam. There are clearly many ways to join a mesh and a foam without such an interlocking structure. To interpret Arnold to disclose such a structure is to read into Arnold subject matter that plainly does not exist.

The claimed invention also requires the mesh reinforcing component to have the proper mesh density (12-80%), which is important to achieve the interlocking of the mesh and the foam. This is another aspect of the claimed invention that is completely absent in Arnold.

For the foregoing reasons Applicants submit that the pending claims distinguish over the cited references and respectfully request allowance thereof.

The Examiner is urged to telephone the undersigned Attorney for Applicants in the event that such communication is deemed to expedite allowance of this application.

Respectfully submitted,

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